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EXAMINER

GHALI, ISIS A D

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/662,775
Filing Date: September 15, 2003
Appellant(s): MARINELLO ET AL.

RONALD R. SANTUCCI
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 19, 2010 appealing from the Office action mailed February 19, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-33 are pending.

Claims 1-12 and 31-33 are withdrawn.

Claims 13-33 rejected and appealed.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

GB 2088714	Marinello et al.	06-1982
US 2,262,711	Ludwin	11-1941
US 5,429,126	Bracken	07-1995
US 6,748,949	Smaldone	06-2004

Depree et al. (Flavour pharmaceutical properties of the volatile sulphur compounds of Wasabi); Food Research International, Vol. 31, No.5, pp 329-337, 1999.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

a) Claims 13-14, 17-19, 21-26, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello (GB 2088714), Ludwin (US 2,262,711), and Smaldone (US 6,748,949).

Applicant Claims

Applicants' claims 13 is directed to a device comprising a facial mask accommodated to allow unobstructed respirator⁷ function of the nostrils and the mouth, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof. Claim 25 is directed to a method of treating sinusitis comprising the step of securing the said device to a person's head.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Marinello teaches using revulsive to treat sinusitis, wherein the preferred revulsive is mustard applied to the skin overlying the sinuses impregnated into a compress and pressed there-against by means of elastic inflatable cushion (page 5, lines 11-20). Mustard contains mustard oil, which is allyl isothiocyanate (page 3, lines 95-96). Marinello teaches impregnation of absorbent dressing (compress) with

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measured amount of the revulsive, applying the dressing to cutaneous surface at point overlying the inflamed organ, and exerting pressure on the dressing using inflatable elastic pad applied as near as possible to the external skin surface overlying the point of inflammation. The pressure produces the following effects: (1) squeezing the dressing and releasing the revulsive, (2) widening of the pores of the skin subjected to pressure, and (3) penetration of the revulsive through the widened pores near the inflamed area. See page 3, lines 7-55. Marinello teaches that the compression of the revulsive to the site of application allows the revulsive to enter the dilated pores of the skin and causes reaction in the deep blood vessels of the body underlying the skin to which the revulsive is applied (page 2, lines 110-115). Marinello teaches avoidance of contact of the compress with the eye (page 5, lines 20-21).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Marinello teaches treating of sinusitis and desired avoidance of eye contact, however, Marinello does not explicitly teach the use of face mask as instantly claimed by claims 13 and 25.

Ludwin teaches medical nebulizer used for treating sinusitis (col.1, lines 1-5). The nebulizer comprises face mask, medicament in a chamber, and pressure provided to vaporize the medicine (col.1, lines 13-39). The medicaments are contained in a sponge member and applied under pressure (col.2, lines 9-12; col.3, lines 21-23). The

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pressure under the mask provides efficient delivery of the drugs and allows penetration of the drug into small pores of the sinus tracts (col.1, lines 36-39).

Ludwin does not explicitly teach that the face mask is unobstructive and covers the nose and mouth.

Smaldone teaches face mask for delivering pressurized drugs from nebulizer wherein the mask comprises features that reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes. The mask covers the mouth and nose and has openings (unobstructed) to release the undesired drug. The mask eliminates discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. See col.5, lines 3-53; Figures 3-5, 7, 11, 13; col.7, lines 6-13, 18-22; col.15, lines 10-22. The mask having holes, therefore is unobstructive as required by claims 13 and 25, and adapted to allow respiration as required by claim 23. The face mask is made of flexible thermoplastic materials as required by claim 24 (col.7, lines 34-36). The figures show that the face mask covers the lower part of the head as required by claim 22.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

At the time of the invention it was known to treat sinusitis by administering dressing impregnated with mustard oil to the skin overlying sinuses and using means of inflatable elastic pad to squeeze the revulsive agent from the compress to the skin as taught by Marinello. Avoidance of eye irritation was also desired.

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Further, delivering medicaments to the sinuses using impregnated dressing and face mask using pressure force was known in the art at the time of the invention as taught by Ludwin.

Additionally, at the time of the invention it was known to use nebulizer to deliver drugs under pressure using masks that cover the nose and mouth that have openings to release the pressure to avoid eye irritation as taught by Smaldone.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses as taught by Marinello, and further use a face mask and pressure taught by Ludwin to cover the impregnated compress of Marinello. One would have been motivated to do so because Ludwin teaches that sinuses can be treated using face mask and applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drug into small pores of the sinus tracts. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask to help penetration of the drug into the pores of sinus tracts to ensure efficient drug delivery to the sinuses.

Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to replace the mask taught by Ludwin with the mask that covers the nose and mouth and has openings as taught by Smaldone. One would have been

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motivated to do so because Smaldone teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask covering the mouth and the nose and having holes wherein the mask is comfortable and eliminates irritation of the eye.

Regarding claim 21 that recites wherein the mask covers an upper part of the face, applicants failed to show unexpected results obtained if the mask cover the upper part of the head.

Regarding claim 19 that recites using rubber pump to inflate the inflatable pad, the prior art recognized applying pressure to deliver mustard from the impregnated compress. Applicants failed to show unexpected results obtained from using the rubber pump to provide pressure over the means used by the prior art to create pressure.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

b) Claims 15, 16, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and

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further in view of the article by Depree et al. (Flavour pharmaceutical properties of the volatile sulphur compounds of Wasabi).

The combined teachings of Marinello with Ludwin and Smaldone are previously discussed as set forth in this office action.

Although Marinello teaches solution of the mustard oil, page 3, line 28, however, the reference does not explicitly teach water and its temperature to activate the revulsive agent as instantly claimed by claims 15, 16, 27 and 28.

Depree teaches that isothiocyanates that is present in mustard oil have the property of decomposition in water and their decomposition in water is temperature dependent; it is more rapidly at 37° C than at 0° C (page 333, left column, first paragraph).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard oil solution impregnated into a compress and use an inflatable elastic cushion and pressurized face mask covering the mouth and the nose and having holes as taught by the combined teachings of Marinello with Ludwin and Smaldone, and further use solution of mustard in water at a temperature below 37° C and above 0° C as taught by Depree. One would have been motivated to do so because Depree teaches that isothiocyanates that is present in mustard have the property of decomposition in water and their decomposition in water is temperature dependent, and decomposition occurs more rapidly at 37° C than at 0° C, so one having ordinary skill in the art would use temperature far lower than 37° C to avoid the decomposition of the active compound. One would reasonably expect to treat

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sinusitis using mustard oil solution in water impregnated into a compress and using an inflatable elastic cushion and pressurized face mask wherein the mustard is provided in water at a temperature below 37° C and above 0° C to ensure solubility of the active agent in the solution without decomposition.

Therefore, the temperature currently claimed falls within that known and taught by the prior art. It has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

See MPEP 2144.05 [R-5].

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

c) Claims 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Marinello with Ludwin and Smaldone, and further in view of the Bracken (US 5,429,126).

The combined teachings of Marinello with Ludwin and Smaldone are previously discussed as set forth in this office action.

Although Ludwin and Smaldone teach face masks, however, the references do not explicitly teach means for securing the mask to the head as instantly claimed by claims 20 and 29.

Bracken teaches respiratory mask that is secure, comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a

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person to attach and remove the respiratory mask with ease and to remove and reinsert the elastic strap repeatedly without constant damage and frequent replacement (col.1, lines 53-60; figures).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard oil solution impregnated into a compress and using an inflatable elastic cushion and pressurized face mask covering the mouth and the nose and having holes as taught by the combined teachings of Marinello with Ludwin and Smaldone, and further use mask having elastic strips to secure the mask of the head of user as taught by Bracken. One would have been motivated to do so because Bracken teaches that such a mask with elastic strips is secure, comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a person to attach and remove the respiratory mask with ease and to remove and reinsert the elastic strap repeatedly without constant damage and frequent replacement. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion and pressurized face mask having securing elastic strips to secure the mask to the user head wherein the mask is secure, comfortable, snug fit to the user's head and further permits mobility and repeated use of the mask.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

Appellants' arguments filed 07/19/2010 have been fully considered but they are not persuasive.

a) Appellants argue that claims 13-14, 17-19, 21-26, and 30 are patentable over Marinello, Ludwin, and Smaldone

- i) *Appellants argue that Marinello fails to disclose absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person as required by claim 13.*

Appellants argue that Marinello is directed to application of a revulsive containing oil of horseradish or oil of mustard in vegetable oil to a cutaneous area of the body to increase the blood circulation to an injury, inflammation or diathesis, the revulsion being applied under pressure that causes the following effects: (1) squeezing of the dressing and releasing of the revulsion, (2) widening of the pores of the skin, and (3) the penetration of the medicine through the pores near the injured area. As a result of these effects, "the medicine will disperse into the blood-stream and in part reach the blood vessels serving the injured, inflamed or diathetic organ. This provokes the enlargement of the vessels, thereby producing an increased flow of blood with curative consequences." Accordingly, the reference teaches only an increased blood flow to an area caused by the application of an oil-based revulsion under pressure. The reference fails to disclose or render predictable absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus as required by the claims.

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In response to this argument, it is argued that Marinello clearly teach and is directed to treatment of sinusitis and Case No. 4, page 5, lines 11-20, of Marinello is directed to using revulsive to treat sinusitis, The reference teaches the preferred revulsive is **mustard** applied to the skin overlying the sinuses impregnated into a compress and pressed there-against by means of elastic inflatable cushion (page 5, lines 11-20). In page 3, lines 73-77, the reference teaches “.....after entering the pores medicine will in part disperse into the blood-stream and in part **reaches the blood vessels serving the injured, inflamed, or diathetic organ**”. The reference further teaches in page 5, lines 27-31, that “the present invention achieves therapeutic results in a variety of situations, where increased blood flow to an internal inflammation, injury or disthesis is necessary.” Therefore, according to the teaching of the reference, **if the internal inflamed organ that needs treatment is sinuses, then the compress impregnated with revulsive (mustard oil) will be applied to the skin overlying the sinus and will be pressed there-against by means of plastic inflatable cushion or pad so the mustard will be delivered through pores of the skin to reach the vessels serving the inflamed sinuses, as case No. 4 of the reference.** According to Marinello, mustard oil will be absorbed from the skin and delivered to the internal organs underling the skin to provide therapeutic effect. In case No. 4 of Marinello, the mustard was applied to the cheek to treat the underlying maxillary sinusitis. **Appellants disclosed in page 8, lines 10-13 of the present specification that:**

“A portion of the medication is dispersed in the blood stream and a portion reaches the vessels feeding the injured area, thus provoking enlargement, greater supply of blood and consequent treatment effects.”

Therefore, Marinello teaches the same mechanism by which the mustard oil reaches the sinuses as disclosed by appellants. Mustard oil absorbed to the blood stream and vessels underlying the skin will be delivered to the surrounding tissues including bones and mucous membranes of the sinuses. In particular the reference teaches treating sinuses and delivering the mustard oils to sinuses under the site of application. **Once the mustard cross the skin barrier, it is inevitable to prevent its access to the blood stream.** Blood vessels are every where in the body including cutaneous tissue, bones forming the sinuses and mucous membranes lining the sinuses.

Therefore all the elements of the present claims are taught by the reference, and delivery of mustard oil through blood stream to different organs and sinuses is within the scope of the present invention.

Appellants argue that the oil of horseradish (or oil of mustard) and vegetable oil composition disclosed in the reference is not suitable for absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus as required by the claims. The vegetable oil, because of its characteristic density, is not suitable to penetrate the skin pores to reach the bones and mucous membranes underlying the skin. Marinello discloses that the "use of vegetable oil solutions...allows

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the solution to be maintained on the body for a longer period of time, thus allowing the revulsives to enter the dilated pores of the skin and cause reactions in the deep blood vessels of the body underlying the skin to which the solution is applied."

In response to this argument, it is argued that, as appellant admits, Marinello clearly teaches absorption and delivery of mustard oil to the blood stream through the dilated skin pores. Vegetable oils are used by the reference as a carrier to maintain the mustard on the skin for sustained or prolonged delivery, but absorption of the mustard oil is not hindered by any means and it reaches the sinuses **as evident by the case No. 4 of the reference wherein sinusitis has been treated**. Burden is on applicants to show that the mustard oil when combined with vegetable oils will not provide treatment of sinusitis. Further, the examiner noticed that the present claims' language does not exclude the presence of vegetable oils or any other carrier for the mustard oil.

- ii) *Appellants argue that Marinello fails to teach a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth*

Appellants argue that Marinello does not teach the use of a face mask as presently claimed in claims 13 and 25. The Ludwin reference is relied upon for such a teaching. Appellants disagree that such a teaching can be found in Ludwin. Ludwin does not teach the face mask is unobstructive and covers the nose and mouth and the Examiner relies on Smaldone to teach a face mask having openings. The openings are alleged to teach unobstructed respiratory function.

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In response to this argument, it is argued that Ludwin clearly teaches face mask that contains drug for delivery to the sinuses driven by pressure. Smaldone is relied upon for teaching the structure of face mask that covers the nose and mouth and release excess drugs so it would not irritate the eyes, as appellants also desired.

(1) *Appellants argue that prima facie obviousness has not been established*

Appellants argue Marinello discloses the application of an oil-based revulsion to cutaneous tissue to stimulate blood flow to an area. Ludwin and Smaldone teach face masks for medical nebulizers. Accordingly, the Examiner is combining a cutaneous drug application system for stimulating blood flow with an inhaled aerosol drug application system and alleging the combination makes obvious the claimed device that includes a facial mask... [that] promotes absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus. Appellants argue that modifying Marinello by Ludwin alone, or in combination with Smaldone, changes the principle of operation of Marinello from a cutaneous system to an inhaled aerosol system, and would be inoperable for use as a cutaneous medicament delivery system to stimulate blood flow to the area thus fails to support a prima facie case of obviousness.

In response to this argument, it is argued that Marinello references clearly teaches and is directed to treating sinusitis as evident by case No. 4. Case No. 4 of the reference shows treating maxillary sinusitis by applying compress impregnated with mustard oil to the cheek overlying the inflamed or diseased sinus. Marinello teaches

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delivery of the mustard oil from the compress by virtue of pressure. Ludwin is concerned with the same problem with which Marinello is concerned, which is treating sinusitis, and teaches drugs to treat sinusitis located under a face mask and are delivered to sinuses by virtue of pressure. Ludwin is relied upon for teaching face mask and pressure to deliver drugs to the sinuses. Ludwin further teaches that applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drug into small pores of the sinus tracts. Smaldone is relied upon for teaching the structure of the mask that covers the nose and mouth and has openings. Smaldone further teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. Delivery of revulsive (mustard oil) from a compress applied to the skin to the sinuses is already taught by Marinello. Therefore, the cited prior art are analogous art, and are in the field of applicant's endeavor and reasonably pertinent to the particular problem with which the applicant was concerned, which is treating sinusitis, and it is reasonable to combine them. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The examiner believes the present invention as a whole as defined by the claims is taught by the combination of the cited prior art and would have been *prima facie* obvious in the meaning of USC 103 (a).

(2) *Appellant argues that combining the references fails to teach the present invention.*

Appellants repeat that there is no indication in Marinello that a device or method was disclosed or rendered predictable that promoted absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus as claimed. Appellants further repeat that the solution disclosed in Marinello is not suitable for penetration through the skin and mucous membranes to underlying bones because of the characteristic density of vegetable oil. Appellants repeat that Ludwin does not teach delivering drugs to the sinuses using an impregnated dressing and a face mask using pressure and the reference is also silent on a "compress" as required by the claimed. Ludwin does not disclose or render predictable a pad applied with pressure to a part of the body to supply medicine. Smaldone does not disclose a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth as claimed. Smaldone recites that in related art masks used for drug delivery in a nebulizer or a metered dose inhaler.

In response to these arguments, the examiner hereby repeats the response regarding Marinello, Ludwin and Smaldone as set forth in this examiner answer. The examiner emphasize that Marinello teaches in page 5, lines 27-31, that "the present invention achieves therapeutic results in a variety of situations, where increased blood flow to an internal inflammation, injury or disthesis is necessary." Therefore, according to the teaching of the reference, **if the internal inflamed organ that needs treatment is sinuses, then the compress impregnated with revulsive (mustard oil) will be applied to the skin overlying the sinus and will be pressed there-against by**

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means of plastic inflatable cushion or pad so the mustard will be delivered through pores of the skin to reach the vessels serving the inflamed organ, as case No. 4 of the reference. According to Marinello, mustard oil will be absorbed from the skin and delivered the internal organs underling the skin to provide therapeutic effect. In case No. 4 of Marinello, the mustard was applied to the cheek to treat the underlying maxillary sinus. **Appellants disclosed in page 8, lines 10-13 of the present specification that:**

“A portion of the medication is dispersed in the blood stream and a portion reaches the vessels feeding the injured area, thus provoking enlargement, greater supply of blood and consequent treatment effects.”

The examiner repeats that Ludwin is relied upon for using face mask and pressure force to deliver drugs to the sinuses, and does not need to teach pad impregnated with mustard oil that is already taught by Marinello. Ludwin is relied upon for replacing the manual pressure that Marinello applied to deliver the mustard oil from the pad with a compressed air pressure supplied from under a face mask. This situation is similar to “automating a manual activity” where the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). Smaldone is relied upon for teaching structure of a face mask that covers the nose and mouth and has openings. The reference teaches the mask is adapted to allow respiration as required by claim 23. The face mask is made of flexible thermoplastic materials as required by claim 24 (col.7, lines 34-36). The

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figures show that the face mask covers the lower part of the head as required by claim 22. Smaldone further teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. Appellants also desired to protect the eye. Delivery of revulsive from skin to the sinuses is already taught by Marinello. One cannot attack the references individually when obviousness is based on combination of the references.

Therefore, combination of the references teaches the present invention as a whole because it would have been obvious to one having ordinary skill in the art at the time of the invention to treat sinusitis using mustard impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses as taught by Marinello, and further use a face mask and apply pressure under the mask as taught by Ludwin to replace the manual pressure applied to the impregnated compress of Marinello. One would have been motivated to do so because Ludwin teaches that drugs can be delivered to sinuses using face mask and applying pressure under the mask will provide efficient delivery of the drugs and allow penetration of the drugs into small pores of the sinus tracts. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask to help penetration of the drug into the pores of sinus tracts and into underlying tissue to ensure

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efficient drug delivery to the sinuses. Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to replace the mask taught by Ludwin with the mask that covers the nose and mouth and has openings as taught by Smaldone. One would have been motivated to do so because Smaldone teaches that such a mask covering the mouth and nose and having holes will reduce the inertia of the drug at the sites most at risk of facial damage and irritation which are the eyes to eliminate discomfort and potential harmful consequences that are associated with masks that leak to the perinasal area and eyes. One would reasonably expect treating sinusitis using mustard oil impregnated into a compress and using an inflatable elastic cushion to press the impregnated compress against the skin overlying the inflamed sinuses, and further use pressurized face mask covering the mouth and the nose and having holes wherein the mask is comfortable and eliminates irritation of the eye.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design

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community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR

INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

b) Appellants argue that claims 15, 16, 27, and 28 are patentable over Marinello, Ludwin and Smaldone, in view of Depree.

Appellants argue that Depree does not cure the defects found in Marinello, Ludwin, and Smaldone. Marinello, Ludwin, and Smaldone, in view of Depree, fail to teach a compress is soaked in water to activate the active ingredient or wherein the water is at a temperature of approximately 10° C as required by the claims. The passage cited by the Examiner refers to the decomposition of isothiocyanates in water

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being temperature dependent. The passage is silent on the activation of isothiocyanates when exposed to water at a particular temperature.

In response to this argument, it is argued that claims 13-14, 17-19, 21-26, and 30 are rendered obvious over the combination of Marinello, Ludwin, and Smaldone, as set forth in this examiner's answer. Depree is relied upon for the sole teaching of the temperature suitable to deliver isothiocyanates. Depree teaches that isothiocyanates that is present in mustard oil have the property of decomposition in water and their decomposition in water is temperature dependent; it is more rapidly at 37° C than at 0° C. This teaching would have suggested to one having ordinary skill in the art not to use temperature about 37° C to avoid decomposition of isothiocyanates and would also lower the temperature of the dressing by soaking in cold water that has temperature below 37° C which is the skin temperature to delay decomposition of isothiocyanates. In view of the term "approximately 10° C", the temperature taught by the prior art reads on the claimed temperature. Further, applicant failed to show unexpected results obtained from using temperature approximately 10° C.

c) Appellants argue that claims 20 and 29 are patentable over Marinello, Ludwin and Smaldone in view of Bracken.

Appellants argue that Bracken fails to correct the defects found in Marinello, Ludwin, and Smaldone.

In response to this argument, it is argued that Bracken is relied upon for the sole teaching method of securing a mask to the face using elastic strap that is secure,

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comfortable and snug fit to head while permitting increased mobility during a course of treatment to enable a person to attach and remove the mask with ease and to remove and reinsert the repeatedly without constant damage and frequent replacement

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Isis A Ghali/
Primary Examiner, Art Unit 1611

Conferees:

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